Introduction to R4BP 3 and Summary of Product Characteristics (SPC) editor

Biocides Stakeholders’ day IT training

27 September 2017

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Let’s imagine that...

- You are a Regulatory Manager of a SME in Finland
- Your company developed a portfolio (family) of disinfectant products sharing:
  - Same active substances with similar composition
  - Similar levels of risk and efficacy
  - Similar uses
- Your plan is to:
  - Market them in (example) Finland and in Germany
  - Capture customers in Germany sensible to nicer branding
  - Eventually sell the product to another company
The Biocides Regulation comes in...

To fulfil your plans you need to:

• Get a National Authorisation (NA) for your product family in Finland

• Get a NA for the same product family, under mutual recognition, in Germany

• Get a NA for only one product of your family as same biocidal product

• Transfer the last NA to another company
How to do that?

BPR requires you to submit applications and seek authorisations via IT tools:

✓ Scientific information on hazards and risks in **IUCLID 6**

✓ Administrative information in **SPC** file (one per each application)

✓ Submission of the application, communications and recording of the evaluations by Competent Authorities in **R4BP 3**
Today we will...

- Introduce the basics of R4BP 3 and SPC editor
- Show you how to use them to get your required authorisation by:
  - Guiding you in a role-play where you will prepare the SPCs and perform the applications in R4BP 3
  - Demonstrating how Competent Authorities are recording their evaluations
- Summarise the next improvements of R4BP 3
SPC editor basics
What is an SPC?

- Standard, electronic and non-confidential component of an authorisation

- It contains public information on
  - Administrative information
  - Concentration ranges,
  - Product and Formulation types
  - Use information
  - Risk management measures
  - Hazard and precautionary statements
How to prepare it?

• To be filled in electronic format

• The information requirements are different for:
  - Single products
  - Product families

• Used for:
  - R4BP 3 data processing
  - Dissemination
  - Comparison

SPC editor
SPC user interface for single product

Each section requires a different type of information
Product Family SPC

Common information on three levels with new SPC editor

1. **Family** – concentration ranges, product types

2. **Meta** - formulation type, authorised uses, risk management measures, hazard and precautionary statements

3. **Product** - specific concentration and trade name
SPC user interface levels for a Product family

- Family
- Meta
- Product
Today your task is to create...

- One SPC for your market area
- One SPC for the market where you're seeking mutual recognition (change market area)
- One SPC for the application of one single same biocidal product (from the family)
R4BP 3 basics
Central hub to comply with legislation and exchange information

R4BP 3

MSCAs
ECHA
Commission

echa.europa.eu
BPR processes

• Requirements in the BPR have been implemented as IT processes in R4BP 3
• Currently almost all of them are available
• For example:
  ✓ National authorisations and mutual recognitions
  ✓ Union and simplified authorisations
  ✓ Active substance approvals
  ✓ Inclusion in Article 95 list and in the Review programme
✓ Considering applications, amendments and cancellations (for authorities) there are about 100 processes
BPR processes as IT workflows

Triggering event → Workflow → Final result

Asset
R4BP 3 User Interface (IND)

<table>
<thead>
<tr>
<th>Task name</th>
<th>Product/Substance name</th>
<th>Active substance</th>
<th>Due date</th>
<th>Case type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sequester</td>
<td>NA-APP scenario 0996</td>
<td>Basic Copper carbonate</td>
<td>30/07/2017</td>
<td>NA-PR5</td>
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<tr>
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<td>side_mk3</td>
<td>side_mk3</td>
<td>29/07/2017</td>
<td>AS-EVA</td>
</tr>
<tr>
<td>Sequester</td>
<td></td>
<td>-</td>
<td>03/06/2016</td>
<td>AS-4RP</td>
</tr>
<tr>
<td>Sequester</td>
<td>Potassium (E,E)-hexa-2,4-dienoate</td>
<td>Potassium (E,E)-hexa-2,4-dienoate (Potassium Sorbate)</td>
<td>03/06/2016</td>
<td>AS-RNL</td>
</tr>
<tr>
<td>Sequester</td>
<td>tyrosine_sub</td>
<td>-</td>
<td>03/06/2016</td>
<td>AS-EVA</td>
</tr>
</tbody>
</table>

**GOOD TO KNOW:**

- **Asset** - In the R4BP 3 context, an asset is a regulatory decision on an application (with a unique asset number) related to either an active substance (e.g., a decision on technical equivalence or the Article 95 list) or a biocidal product (e.g., a national authorisation or a Union authorisation).

- **Case** - A case relates to an application and is created after the successful submission of an application (with a unique case number) in R4BP 3 by the Industry users. It includes all the steps in the application process which lead to the creation of, or update of, an asset (the regulatory decision). The purpose of a case is to manage and view the progress of the submission by both the Industry and Authority users.

- **Event** - An event is a step whereby information is submitted that is needed in the handling / processing of an application. Examples include the submission of an application, the submission of additional information, or the request of the authorities, fee payment, and the communication of a decision.

- **Task** - A working item that is created and assigned to specific user groups (Industry or Authority users). A task is created in order to perform and complete certain actions (e.g., request for additional information) that are required from the users. These requests are completed through task items within a defined time period. The task is identified by the task name and is related to a particular case number.
R4BP 3 User Interface (AUTH)
Triggering event: new Application

- Initial submissions
- Grouped applications (under development)
- Subsequent processes (mutual recognition in sequence)
Assets

- Positive outcome on an application
- Unique asset number
Process steps as workflow tasks
Tasks – You are required to act

- E.g. Resubmission & Reply (*Process, for Authorities*)
- Due date!
- Email alerts to applicant
- Search / filter / export
Sequence of tasks = Case
Cases – Your submissions

- All ongoing processes
- Detailed permanent event history
- Email alerts to applicant
Messages – Your Communication

- Inbox, Sent, Search
- Attachments
- Permanent records
- Email alerts to applicant
R4BP 3 User Interface (IND)
R4BP 3 User Interface (AUTH)
Role play
Let’s get the authorisations!

• You will have to work together in teams, playing three roles: Industry, Authority and ECHA
• You need to get three authorisations, so you can swap in every process, if you feel like
• First create your SPCs, then submit the applications
• Credentials in the room document
• If needed, test data here: http://bit.ly/biocidesIT
• Our observers will help you!
<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:45 – 11:10</td>
<td>Introduction to R4BP 3 and SPC editor</td>
</tr>
<tr>
<td>11:10 – 11:50</td>
<td>Exercise 1 (SPC)</td>
</tr>
<tr>
<td>11:50 – 12:15</td>
<td>Exercise 2 (NA-APP, NA-MRP)</td>
</tr>
<tr>
<td>12:15 – 12:45</td>
<td>Sandwich break</td>
</tr>
<tr>
<td>12:45 – 13:25</td>
<td>Exercise 2 (NA-APP, NA-MRP)</td>
</tr>
<tr>
<td>13:25 – 13:45</td>
<td>Exercise 3 (NA-BBS)</td>
</tr>
<tr>
<td>13:45 – 14:00</td>
<td>New features of R4BP 3 and SPC editor</td>
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<tr>
<td>17:00</td>
<td>END</td>
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</table>

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Exercise 1 – Create SPCs (40’")
Create a product family SPC
**SPC information for your Product family**

You will have to fill in the following information in the SPC

<table>
<thead>
<tr>
<th>Family</th>
<th>Hydrogen peroxide</th>
<th>Ethanol</th>
<th>Water</th>
<th>PT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meta 1</td>
<td>20-48%</td>
<td>0.5-1%</td>
<td>51-79.5%</td>
<td>2</td>
</tr>
<tr>
<td>Product 1</td>
<td>48%</td>
<td>1%</td>
<td>51%</td>
<td></td>
</tr>
<tr>
<td>Product 2</td>
<td>40%</td>
<td>0.5%</td>
<td>59.5%</td>
<td></td>
</tr>
<tr>
<td>Meta 2</td>
<td>20-25%</td>
<td>0.5-0.8%</td>
<td>74.2-79.5%</td>
<td>3</td>
</tr>
<tr>
<td>Product 1</td>
<td>20 %</td>
<td>0.5%</td>
<td>79.5%</td>
<td></td>
</tr>
<tr>
<td>Product 2</td>
<td>25%</td>
<td>0.8%</td>
<td>74.2%</td>
<td></td>
</tr>
</tbody>
</table>
Create a product family SPC for another market area
Create a product family SPC for a same biocidal (single) product
Exercise 2 –NA-APP, NA-MRP (65’")
Workflow: National Authorisation (NA-APP)

- **COM**
- **MSCA**
- **ECHA**

**Business Rules Check**

1. Accept
2. Validate
3. Evaluate & decide

**Resubmit**

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## Workflow: Mutual recognition (NA-MRP)

<table>
<thead>
<tr>
<th>COM</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>MSCA</td>
<td></td>
</tr>
<tr>
<td>ECHA</td>
<td></td>
</tr>
</tbody>
</table>

**Business Rules Check**
- Accept
  - Validate
  - Evaluate & decide

**Resubmit**

[echa.europa.eu](http://echa.europa.eu)
Apply for National Authorisation

- CC-APP - Classification of a change to a product authorisation
- CS-APP - Application for chemical similarity
- DI-SUB - Declaration of interest to notify
- ET-NOT - Notification of experiment or test
- IN-REA - Inquire to share data (for active substance)
- IN-REB - Inquire to share data (for biocidal product)
- **NA-APP** - Application for national authorisation
- NA-BBP - National authorisation of same biocidal product (pending)
Select authorities

You are tester_one on behalf of Company One (FI)

Submission for application for national authorisation (NA-APP)

Select authorities

Please start the submission process for your application by filling all required information.

*Evaluating authority: Finland

If you want to seek mutual recognition, please indicate the relevant Member States from the

Concerned Member States

- Germany
  - Greece
  - Hungary
  - Iceland
  - Ireland
  - Italy
  - Latvia
  - Lithuania
Upload IUCLID 6 dossier

Make sure it is a IUCLID 6 dossier!
Upload all relevant SPCs
Submit application

Your next steps

Your submission numbers are:
Reference Case:
BC-BR001344-46/1 (MSCA-Germany)
Concerned Case(s):
BC-FA001345-74/1 (MSCA-Finland)

Note that receipt of this message does not guarantee that your application is correct.

1. If your application is in the correct format you will receive a message
2. Monitor your application progress in the “Events History” tab under “Manage application”.

If you need to contact the ECHA Helpdesk regarding your application please use your reference case number.
ECHA – Business rules check for case 1 and 2
MSCA – Accept for case 1 and 2
MSCA – Validate for case 1 and 2
MSCA – Evaluate for case 1 and 2
Exercise 3 – Apply for NA-BBS (20’")
<table>
<thead>
<tr>
<th>ECHA</th>
<th>Resubmit</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSCA</td>
<td>Business Rules Check</td>
</tr>
<tr>
<td>COM</td>
<td>Evaluate &amp; decide</td>
</tr>
<tr>
<td></td>
<td>Accept</td>
</tr>
<tr>
<td></td>
<td>Validate</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Apply for Same Biocidal Product

- NA-APP - Application for national authorisation
- NA-BBP - National authorisation of same biocidal product (pending)
- NA-BBS - National authorisation of same biocidal product (authorised)

Set reference details

Please provide below your reference number (asset)

* Reference asset number:
Collect the Case number

Your next steps

Submission number BC-LU002857-12/1

Note that receipt of this message does not guarantee that your application is accepted for processing. Verification of the format must first be completed by R4BP 3, therefore it is important that you follow the advice below in case further action (such as a resubmission) is required from you.

1. If your application is in the correct format you will receive a message in your R4BP 3 message tab with further instructions. If your application is not in the correct format you will receive a task item with instructions on how to resubmit a new one. Please pay attention to the resubmission deadline.
2. Monitor your application progress in the "Events History" tab under the case details page.

If you need to contact the ECHA Helpdesk regarding your application please provide the submission number.

Close
Process the application

- MSCA accept
- Validate
- Evaluate & Decide

Please select one of the following allowed actions based on your decision:

- Provide your decision
- Validate
- Request additional Info
- Approve application
- Request additional Info
- Do not approve
Exercise 4 – Transfer an asset (optional)
Add asset transfer
Accept asset transfer